

DEVELOPMENT AND VALIDATION OF NEW ANALYTICAL METHODS FOR THE QUANTIFICATION OF CLOFARABINE IN BULK AND PHARMACEUTICAL DOSAGE FORM

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Received: 21 May 2021

Accepted: 24 May 2021

Published: 26 May 2021

ABSTRACT

The aim of the method is to develop an analytical procedure for the determination of Clofarabine in Pharmaceutical Formulations. The analytical procedure for determination of Assay in finished product of Clofarabine Injection, 1mg/mL is an In-House procedure. The Chromatographic system consisted of a Shimadzu Class VP Binary pump LC-10ATvp, SIL-10ADvp Auto sampler, CTO-10Avp Column Temperature Oven, SPD-10Avp UV-Visible Detector. All the components of the system are controlled using SCL-10Avp System Controller. Data acquisition was done using LC Solutions software.

KEYWORDS: *Clofarabine, HPLC, Method Development, Validation, ICH Guidelines*